

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

**WEST et al.**

Serial No.: 10/524,090

Filed: February 9, 2005

Art Unit: (Not yet assigned)

Examiner: (Not yet assigned)

Atty. Docket No.: 05-205-US

**CARRIER**

VIA EXPRESS MAIL LABEL NO. EV336822117US

MAIL STOP PCT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

This Information Disclosure Statement is filed in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98. The items listed on the enclosed Form PTO-1449 may be deemed to be pertinent to the above-identified application and are made of record to assist the Patent and Trademark Office in its examination of this application. The Examiner is respectfully requested to fully consider the items and to independently ascertain their teaching.

1. ☒ Enclosed is PTO Form 1449 (and a duplicate thereof).
2. ☒ Items listed on the enclosed Form PTO-1449 are not in the English language.
  - ☐ For each of the following items, an English-language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed:
  - ☐ For each of the following items, a concise explanation of that item is incorporated in the specification of the above-identified application:
  - ☐ For each of the following items, a corresponding U.S. or other English-language patent is enclosed. Please consider the U.S. or other English-language patents in accordance with the procedure set forth in MPEP § 609:
  - ☒ that are U.S. patents or publications, no copies are being provided in accordance with the Official Gazette Notice of August 5, 2003.

3. ☐ **Submission in Accordance with 37 CFR § 1.98(d).**

Any copy of the items listed on the enclosed Form PTO-1449 that is not enclosed with this Information Disclosure Statement was previously cited by or submitted to the Patent and Trademark Office in Application Serial No. [Ser. No.], filed [Date], of which the present application relies upon for an earlier filing date under 35 U.S.C. 120.

4. ☒ **Submission in Accordance with 37 CFR § 1.97(b).**

This Information Disclosure Statement is being filed

- ☐ With the application;
- ☐ Within three months of the filing date of a national application;
- ☐ Within three months of the date of entry of the national stage in an international application; or
- ☒ Before the mailing date of a first Office Action on the merits,

and NO FEE is due for consideration of this Information Disclosure Statement.

5. ☐ **Submission in Accordance with 37 CFR 1.97(c).**

This Information Disclosure Statement is being filed before the first mailing date of either

- ☐ A final action under § 1.113; or

☐ A notice of allowance under § 1.311.

☐ A fee is due for consideration of this Information Disclosure Statement and the fee is paid below; or

☐ This Information Disclosure Statement is accompanied by one of the certifications pursuant to 37 CFR § 1.97(e), and NO FEE is due for consideration of this Information Disclosure Statement.

6. ☐ **Submission in Accordance with 37 CFR 1.97(d).**

This Information Disclosure Statement is being filed after the mailing date of either

☐ A final action under § 1.113; or

☐ A notice of allowance under § 1.311,

whichever comes first, but before payment of the issue fee, and is accompanied by

a. One of the certifications pursuant to 37 CFR § 1.97(e), which is set forth below;

b. The attached petition requesting consideration of this Information Disclosure Statement; and

c. The petition fee under 37 CFR § 1.17(i)(1), which is paid below.

7. **Certification Pursuant to 37 CFR 1.97(e).**

☐ The undersigned certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application not more than three months prior to the filing of this Information Disclosure Statement; or

☐ The undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, or to my knowledge after making reasonable inquiry, was known to any individual designated in 37 CFR § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

8. **Fee Payment Being Made.**

☐ Enclosed

☐ \$180.00 fee for submission under 37 CFR § 1.97(c).

☐ \$180.00 fee for submission under 37 CFR § 1.97(d).

☐ A check in the amount of \$[Amount] to cover the fee payment is enclosed.

- ☐ Charge the fee to Deposit Account No. 18-0582. A duplicate copy of this communication is attached.
- ☒ The Director is hereby authorized to charge payment of any additional fees associated with this Information Disclosure Statement or credit any overpayment to Deposit Account No. 18-0582. A duplicate copy of this communication is enclosed.

Respectfully submitted,



James G. Dilmore  
Reg. No. 51,618

Dated: July 5,, 2006

REED SMITH LLP  
P.O. Box 488  
Pittsburgh, PA 15230-0488  
(412) 288-3813

Agent for Applicants

<b>FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (MODIFIED) U.S. PATENT AND TRADEMARK OFFICE</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <b>(37 CFR 1.98(b))</b>	<b>ATTY. DOCKET NO.</b>  05-205-US	<b>SER. NO.</b>  10/524,090
	<b>APPLICANT</b>  WEST et al.	
	<b>FILING DATE</b>  February 9, 2005	<b>GROUP</b>

#### U.S. PATENT DOCUMENTS

Examiner Initial	Cite No.	Patent Number	Issue Date	Patentee	Class/ Subclass	Filing Date
_____		5,583,105	12/1996	Kovács et al.		
_____		6,479,540	11/2002	Constantinides et al.		
_____						

#### FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Examiner Initial	Cite No.	Document Number	Publication Date	Country or Patent Office	Class/ Subclass	Translation Yes/No
_____		9621440	7/1996	WO		
_____		0240033	5/2002	WO		
_____		0240034	5/2002	WO		
_____		03011303	2/2003	WO		
_____		03049774	6/2003	WO		
_____						

#### OTHER DOCUMENTS

(Including Author, Title, Date, Relevant Pages, Place of Publication)

Examiner Initial	Cite No.	
_____		Morgan T. et al., "Enhanced Transdermal Delivery of Sex Hormones in Swine with a Novel Topical Aerosol", JOURNAL OF PHARMACEUTICAL SCIENCES, Vol. 87, No. 10, Oct 1998, pp. 1219-1225
_____		Potts, R. et al., "Predicting Skin Permeability", PHARMACEUTICAL RESEARCH, Vol. 9, No. 5, 1992, pp. 663-669
_____		Ostrenga, J., et al. "Significance of Vehicle Composition I: Relationship between Topical Vehicle Composition, Skin Penetrability, and Clinical Efficacy", JOURNAL OF PHARMACEUTICAL SCIENCES, Vol. 60, 1971, pp. 1175-1179
_____		Barrett, C. et al., "The Effect of Particle Size and Vehicle on the Percutaneous Absorption of Fluocinolone Acetonide", BRIT. J. DERM., Vol. 77, 1965, pp. 576-578
_____		

EXAMINER	DATE CONSIDERED
/Gigi Huang/	02/29/2008

**EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.**

ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /G.H./